IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

UNITED STATES OF AMERICA, Plaintiff, v. JONLLY FRUITS, INC., a corporation, and BARTOLO PÉREZ ROMÁN, an individual, Defendants.	CIVIL NO. _____

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

INTRODUCTION

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to permanently enjoin and restrain Jonlly Fruits, Inc., a corporation, and Bartolo Pérez Román, individual (collectively, "Defendants"), from violating (a) 21 U.S.C. § 331(k), by causing any food that is held for sale after shipment of one or more components in interstate commerce to become adulterated and misbranded within the meaning of 21 U.S.C. § 342(a)(4).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Jonlly Fruits ("Jonlly") is a Puerto Rico corporation that manufactures, labels, and distributes a variety of beverages, including 100% orange juice, juice concentrates, and fruit juice beverages. Jonlly is located at Carr 831 Km 2.7, Bo. Minillas, Bayamon, Puerto Rico, within the jurisdiction of this Court.

5. Jonlly's products are sold under its own label, "Jonlly," as well as "Natural Tropic," "Selectos," and several other private-label brands.

6. Defendant Bartolo Pérez Román is Jonlly's President. He has authority over all aspects of Jonlly's operations, including the receipt of raw materials, manufacturing, quality control, storage, packing, sale, and distribution of the firm's products. He also has the ability to hire and fire employees, and to detect, correct, and prevent deficiencies at Jonlly. Defendant Pérez Román is also responsible for the labeling content for all of the firm's products, including those manufactured for private-label brands. All of Jonlly's employees report directly to Defendant Pérez Román.

7. Defendants manufacture their 100% juice and fruit juice beverages from raw materials and juice concentrates. The juice concentrates originate from, among other countries, the Dominican Republic, Jamaica, Mexico, Brazil, and Ecuador. Additionally, Defendants use sodium benzoate as an ingredient in nearly all of their products, which is made in China.

8. All of the processing, packing, and labeling takes place on-site at Defendants' facility. Jonlly currently has 26 employees, produces approximately 300,000 gallons of juice each month, and generates roughly $2 million in sales revenue each year.

9. Defendants distribute their finished beverages to chain supermarkets, local schools, and department stores located throughout Puerto Rico.

REGULATORY FRAMEWORK

10. Defendants' juice is "food" within the meaning of 21 U.S.C § 321(f).

11. In order to prevent or minimize potential food safety hazards known to occur during juice manufacturing, a juice processor must follow the juice Hazard Analysis and Critical Control Point ("HACCP") regulations found in 21 C.F.R. Part 120.

12. Under the juice HACCP regulations, every juice processor must develop, or have developed for it, a written hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur during processing of each type of juice produced and to identify control measures that the processor will apply to control those hazards. 21 C.F.R. § 120.7(a).

13. Whenever a hazard analysis identifies one or more food safety hazards that are reasonably likely to occur during processing, the processor must have and implement a written HACCP plan to control for the identified hazards. 21 C.F.R. § 120.8.

14. A HACCP plan must identify critical control points, which are points, steps, or procedures in a food manufacturing process at which controls can be applied to prevent, eliminate, or reduce to acceptable levels, a food safety hazard. 21 C.F.R. §§ 120.3(d), 120.7(a)(5), 120.8(b)(2).

15. At each critical control point, a HACCP plan must also identify critical limits, which are the maximum or minimum values to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level, the occurrence of the identified food safety hazard(s). 21 C.F.R. §§ 120.3(e), 120.8(b)(3).

16. The juice HACCP regulations also require juice processors to include control measures in their HACCP plan that will consistently produce, at a minimum, a significant

reduction (referred to as a "5-log reduction") of the most resistant microorganism of public health significance likely to occur in the juice. 21 C.F.R. § 120.24(a). While the HACCP regulation does not specify any particular processes that must be employed to achieve the 5-log reduction, the most commonly-used process involves juice pasteurization through heat treatment or ultraviolet light. To achieve the 5-log reduction, juice processors are required to use a treatment process that is applied directly to the juice. 21 C.F.R. § 120.24(b).

17. The juice HACCP regulations further require juice processors to have and implement a sanitation standard operating procedure that addresses sanitation conditions and practices before, during, and after processing. 21 C.F.R. § 120.6. Juice processors must monitor, with sufficient frequency, their sanitation conditions and practices used during processing to ensure, at a minimum, that they conform with conditions and practices known as current good manufacturing practice ("cGMP") for manufacturing, packing, or holding human food, see, 21 C.F.R. Part 110. 21 C.F.R. § 120.6(b). CGMP applies in determining whether the facilities, methods, practices, and controls used to process juices are safe, and whether the food has been processed under sanitary conditions. 21 C.F.R. § 120.5; see also 21 C.F.R. § 110.5.

18. Juice products that are processed without adhering to the requirements of 21 C.F.R. Part 120 and cGMP are adulterated within the meaning of 21 U.S.C. § 342(a)(4). 21 C.F.R. § 120.9.

19. Defendants are subject to the juice HACCP regulations because they manufacture juice as defined in 21 C.F.R. § 120.1, such as 100% orange juice and orange concentrate, and because Defendants' manufacturing operations constitute "processing," as defined by 21 C.F.R. § 120.3(j)(1).

DEFENDANTS' VIOLATIONS OF THE ACT

20. Defendants violate 21 U.S.C. § 331(k) by causing juice to become misbranded while it is held for sale after shipment of one or more components in interstate commerce.

21. Certain of Defendants' juice products are misbranded within the meaning of 21 U.S.C. § 343(a)(1) because they are labeled in a false and misleading manner because their labels claim that the products are "natural," and "100% natural juice," even though the labeling and product formulation sheets indicate that the products contain chemical additives such as sodium benzoate, and artificial colorants Yellow #5 and Red #40.

22. Certain of Defendants' juice products are misbranded within the meaning of 21 U.S.C. § 343(r)(1)(A) because their labels bear nutrient content claims, such as "Light," "100% Vitamin C," "Rich in Calcium," "No Sugar," but the products bearing these claims do not meet the requirements set forth in FDA's regulations, 21 C.F.R. Part 101.

23. Certain of Defendants' juice products are misbranded under 21 U.S.C. § 343(i)(1) because they fail to bear the common or usual name of the food.

24. Defendants also violate 21 U.S.C. § 331(k) causing juice to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), while such articles are held for sale after shipment of one or more components in interstate commerce.

25. Defendants' juice products are adulterated within the meaning of 21 U.S.C. § 342(a)(4) because Defendants fail to comply with cGMP and, thus, their juice products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth.

26. Defendants' 100% juice products are also adulterated because Defendants fail to comply with the juice HACCP regulations, which renders such products adulterated under

21 U.S.C. § 342(a)(4) because they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

DEFENDANTS' HISTORY OF VIOLATIONS

Inspection History

27. FDA's San Juan District Office has inspected Defendants' facility eight times, most recently on March 15, 16, 22, April 3, and June 6, 2012 ("the 2012 Inspection"). At the close of each inspection, FDA issued Defendants a List of Inspectional Observations ("FDA 483"), documenting the investigator's observed violations.

The 2012 Inspection

28. During the 2012 Inspection, the FDA investigator observed violations, including Defendants' failure to:

(a) Comply with the juice HACCP regulations by having a written HACCP plan for their 100% juice products, including 100% orange juice and orange juice concentrate;

(b) Comply with the HACCP regulations by applying a "5-log reduction" process to the final product, such as pasteurization through heat treatment or ultraviolet light, to control for microorganisms of public health significance likely to occur, e.g., Salmonella species and Listeria monocytogenes ("L. mono.");

(c) Have a protective cover over their mixing tank to prevent water from dripping into the tanks from the pipe directly overhead;

(d) Adequately clean equipment and food-contact surfaces, such as the sesame grinder, which contained mold, and the bottle-capping machine, which was rusted;

(e) Store toxic cleaning and sanitizing compounds, such as hypochlorite solution, in a secure manner and in clearly-identified containers to prevent contamination;

(f) Employ proper employee practices to avoid contamination of finished product with filth;

(g) Properly maintain storage areas in a sanitary condition;

(h) Exclude pests, including live and dead cockroaches, ants, and rodents from the processing area; and,

(i) Maintain employee hand-washing, hand-sanitizing, and toilet facilities.

29. During the 2012 Inspection, the FDA investigator also discussed her observations with Defendants regarding Defendants' violative labeling practices. The investigator informed Defendants that certain of their fruit juice beverages were inappropriately labeled, as follows:

(a) With the claim "Light," because they do not include any reference food on the label as required by 21 C.F.R. §§101.13(j) and 101.56(b);

(b) With nutrient-content claims such as "100% Vitamin C," because they do not describe the percentage of Vitamin C in relation to the Reference Daily Intake ("RDI") for the vitamin as required by 21 C.F.R. § 101.13(q)(3);

(c) With the claim "Natural," because the product formulation sheets list chemical additives such as sodium benzoate, and artificial colorants, including Yellow #5 and Red #40;

(d) With the claim "No Sugar" because the nutrition facts panel on the label lists between 5 and 11 grams of sugar per serving for each of the beverages bearing this claim; however, the regulations allows such a claims to be made only on foods that contain less than 0.5 g of sugars per serving. 21 C.F.R. § 101.60(c);

(e) Because they do not contain a proper statement of identity on the principal display panel explaining what the product is, e.g., "orange juice," or "fruit juice beverage," as required by 21 C.F.R. §101.3; and,

(f) Because they do not declare sub-ingredients that include allergens such as milk derivatives and soy lecithin.

30. On June 6, 2012, the FDA investigator held a close-out meeting with Defendants, during which Defendant Pérez Román acknowledged the investigator's observations included in the FDA 483, and also stated that he would respond with a corrective action plan and a written response to the inspection within fifteen (15) days. During the inspection the firm also initiated a voluntary recall, however, this recall is inadequate because it focused only on products containing undeclared allergens and did not include any of Defendants' other adulterated or misbranded products.

The 2010 Inspection

31. FDA previously inspected Defendants' operations between September 20 and October 5, 2010 ("the 2010 Inspection"). During the inspection, the FDA investigator observed violations similar to those observed during the most recent inspection, including Defendants' failure to:

(a) Apply a 5-log reduction process to the final product to control for microorganisms of public health significance likely to occur, e.g., Salmonella species and L. mono;

(b) Have a protective cover over their mixing tank to prevent water from dripping into the tanks from the pipe directly overhead;

(c) Store toxic cleaning and sanitizing compounds, such as chlorine solution, in a secure manner and in clearly-identified containers to prevent contamination;

(d) Properly clean and sanitize equipment and food-contact surfaces; and,

(e) Properly maintain employee hand-washing, hand-sanitizing, and toilet facilities.

32. Although Defendants had completed a written hazard analysis for their juice products during this inspection, they still failed to comply with the juice HACCP regulations because they failed to develop a written HACCP plan to demonstrate how they will control for the food safety hazards they identified in their hazard analysis. FDA explained this deficiency to management during the close-out meeting held on October 5, 2010, and also in a Warning Letter that FDA sent to Defendant Pérez Román on March 23, 2011.

33. During the 2010 Inspection, the FDA investigator also discussed her observations with Defendants regarding Defendants' violative labeling practices. Specifically, the investigator informed Defendants that certain of their fruit juice beverages were inappropriately labeled, as follows:

(a) With the claim "Light," because they did not include any reference food on the label; and

(b) With the claim "Natural," because the product formulation sheets list chemical and synthetic additives.

34. The FDA investigator discussed her findings with Defendant Pérez Román during a close-out meeting held on October 5, 2010 during which she issued the FDA 483 to Defendant Pérez Román.

The 2009 Inspection

35. FDA previously inspected Defendants' operations between July 27 and August 6, 2009 ("the 2009 Inspection"). During the inspection, the FDA investigator observed violations similar to those observed during the most recent two inspections, including Defendants' failure to:

(a) Comply with the HACCP regulations by having an adequate written HACCP plan for their 100% orange juice;

(b) Follow proper employee practices to avoid contamination of finished product with filth;

(c) Adequately clean and sanitize equipment and food-contact surfaces; and,

(d) Exclude pests, including flying insects and rodents, from the processing area.

36. During the 2009 inspection, the FDA investigator also discussed her observations relating to Defendants' labeling. The investigator informed Defendants that certain of their fruit juice beverages were inappropriately labeled with the claim "Natural," because the product formulation sheets list chemical and synthetic additives.

37. FDA also inspected Defendants' operations between March 31 and April 4, 2008 ("the 2008 Inspection"); March 5 and 30, 2007 ("the 2007 Inspection"); August 18 and 26, 2004 ("the 2004 Inspection"); June 11 and 14, 2002 ("the 2002 Inspection"); and April 14 and 25, 2000 ("the 2000 Inspection"). During each of these inspections, FDA investigators observed similar violations to those observed in the 2009, 2010, and 2012 inspections, including juice HACCP, cGMP, and labeling violations.

Prior Notice

38. Defendants have received ample notice that their operations violate the law and that continued violations could lead to an injunction against them. FDA has conducted eight inspections of Defendants' facility and issued an FDA 483 at the close of each inspection. Additionally, in response to the 2000 Inspection, FDA issued a Warning Letter to Defendants on September 5, 2000 documenting their violations. Defendants did not respond to this Warning Letter.

39. In response to the FDA 483 issued at the close of the 2002 Inspection, Defendants submitted a written response to FDA's San Juan District, which was inadequate. FDA then held a regulatory meeting with Defendants on June 12, 2003 to discuss the firm's response to its on-going violations.

40. Despite the Warning Letter and regulatory meeting, Defendants continued to violate the Act. FDA issued a 9-item FDA 483 at the close of the 2004 Inspection. FDA also sent Defendants an Untitled Letter following the 2004 Inspection. Defendants failed to respond to FDA's Untitled Letter.

41. Again on March 17, 2005, FDA held a regulatory meeting with Defendants. During this meeting, Defendants promised to correction their violations.

42. Despite this second regulatory meeting, Defendants have continued to violate the law, as observed during the 2007 Inspection, which resulted the issuance of a 14-item FDA 483. During the 2007 Inspection, the FDA investigator also discussed several labeling deficiencies with Defendant Pérez Román, who again promised corrections.

43. Despite Defendants' promises, FDA documented continued violations during the 2008, 2009, and 2010 Inspections. On March 23, 2011, following FDA's 2010 Inspection, FDA sent Defendants a second Warning Letter documenting their repeated violations. That Warning Letter clearly stated, "[f]ailure to promptly correct these violations may result in regulatory action without further notice, including seizure of violative product(s) and/or injunction against the manufacturers or distributors of violative products." Defendants did not respond to this Warning Letter.

44. While Defendants did initiate a voluntary recall of certain fruit juice beverages on April 4, 2012 in response to the 2012 inspection, this recall is inadequate because it focused only

on products containing undeclared allergens, but it did not include any of Defendants' other adulterated or misbranded products.

45. Despite multiple inspections, numerous warnings from FDA, and Defendants' promises that the violations would be remedied, Defendants have failed to institute effective measures to bring their operations into compliance with the law.

46. Based on their repeated course of conduct, Defendants, unless restrained by order of this Court, will continue to violate the law.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing to be done any of the following acts:

(a) Violating 21 U.S.C. § 331(k), by causing food that Defendants hold for sale after shipment of one or more of its components in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 343(a)(1), (r)(1)(A), and/or (i)(2); and

(b) Violating 21 U.S.C. § 331(k), by causing food that Defendants hold for sale after shipment of one or more of its components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from receiving, processing, preparing, packing, holding, labeling or distributing food, unless and until the labeling for all articles of food in Defendants' possession or under Defendants' custody or

control comply with the Act and its implementing regulations, and Defendants bring their processing operations into compliance with cGMP and the juice HACCP regulations, the Act, and its implementing regulations in a manner that has been found acceptable by FDA.

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receipt, processing, preparing, packing, holding, labeling or distribution of any food to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

IV. Order that Plaintiff be awarded costs and other such relief as the Court deems just and proper.

DATED this 15 day of January, 2013.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby acknowledges that the foregoing Complaint was served via email and FEDEX, by request, upon below-listed counsel for all defendants on this 15th day of January, 2013.

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